

modification of the method by the applicant.

(c) Any tests by either party that are to be witnessed or observed by the other party shall be conducted at a time and place mutually agreeable to both parties.

**§ 53.7 Testing of methods at the initiative of the Administrator.**

(a) In the absence of an application for a reference or equivalent method determination, the Administrator may conduct the tests required by this part for such a determination, may compile such other information as may be necessary in his judgment to make such a determination, and on the basis of the tests and information may determine that a method satisfies applicable requirements of this part.

(b) In the absence of an application requesting the Administrator to consider revising an appendix to part 50 of this chapter in accordance with § 53.16, the Administrator may conduct such tests and compile such information as may be necessary in his judgment to make a determination under § 53.16(d) and on the basis of the tests and information make such a determination.

(c) If a method tested in accordance with this section is designated as a reference or equivalent method in accordance with § 53.8 or is specified or designated as a reference method in accordance with § 53.16, any person who offers the method for sale as a reference or equivalent method thereafter shall assume the rights and obligations of an applicant for purposes of this part with the exception of those pertaining to submission and processing of applications.

[40 FR 7049, Feb. 18, 1975, as amended at 41 FR 11256, Mar. 17, 1976]

**§ 53.8 Designation of reference and equivalent methods.**

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a reference method or equivalent method (as applicable), and a notice of the designation shall be submitted for publication in the FEDERAL REGISTER not later than 15 days after the determination is made.

(b) A notice indicating that the method has been determined to be a reference method or an equivalent method shall be sent to the applicant. This notice shall constitute proof of the determination until a notice of designation is published in accordance with paragraph (a) of this section.

(c) The Administrator will maintain a current list of methods designated as reference or equivalent methods in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available for inspection or copying at EPA Regional Offices.

**§ 53.9 Conditions of designation.**

Designation of a candidate method as a reference method or equivalent method shall be conditioned on the applicant's compliance with the following requirements. Failure to comply with any of the requirements shall constitute a ground for cancellation of the designation in accordance with § 53.11.

(a) Any method offered for sale as a reference or equivalent method shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser.

(b) Any method offered for sale as a reference or equivalent method shall generate no unreasonable hazard to operators or to the environment during normal use or (if the method is automated) during normal use or when malfunctioning.

(c) Any analyzer or PM<sub>10</sub> sampler offered for sale as a reference or equivalent method shall function within the limits of the performance specifications referred to in § 53.20(a) or § 53.40(a), as applicable, for at least one year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

(d) Any analyzer or PM<sub>10</sub> sampler offered for sale as a reference or equivalent method shall bear a prominent, permanently affixed label or sticker indicating that the analyzer or PM<sub>10</sub> sampler has been designated by EPA as a reference method or as an equivalent method (as applicable) in accordance with this part.

(e) If an analyzer is offered for sale as a reference or equivalent method but

has one or more selectable ranges, the label or sticker required by paragraph (d) of this section shall be placed in close proximity to the range selector and shall indicate clearly which range or ranges have been designated as parts of the reference or equivalent method.

(f) An applicant who offers analyzers or PM<sub>10</sub> samplers for sale as reference or equivalent methods shall maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such analyzers or PM<sub>10</sub> samplers. For a period of seven years after publication of the reference or equivalent method designation applicable to such an analyzer or PM<sub>10</sub> sampler, the applicant shall notify all ultimate purchasers of the analyzer or PM<sub>10</sub> sampler within 30 days if the designation has been cancelled in accordance with § 53.11 or § 53.16 or if adjustment of the analyzer or PM<sub>10</sub> sampler is necessary under § 53.11(b).

(g) If an applicant modifies an analyzer or PM<sub>10</sub> sampler that has been designated as a reference or equivalent method, the applicant shall not sell the analyzer or PM<sub>10</sub> sampler as modified as a reference or equivalent method nor attach a label or sticker to the analyzer or PM<sub>10</sub> sampler as modified under paragraph (d) or (e) of this section until he has received notice under § 53.14(c) that the existing designation or a new designation will apply to the analyzer or PM<sub>10</sub> sampler as modified or has applied for and received notice under § 53.8(b) of a new reference or equivalent method determination for the analyzer or PM<sub>10</sub> sampler as modified.

[40 FR 7049, Feb. 18, 1975, as amended at 41 FR 11256, Mar. 17, 1976; 52 FR 24728, July 1, 1987]

#### **§ 53.10 Appeal from rejection of application.**

Any applicant whose application for a reference or equivalent method determination has been rejected may appeal the Administrator's decision by taking one or more of the following actions:

(a) The applicant may submit new or additional information in support of the application.

(b) The applicant may request that the Administrator reconsider the data and information already submitted.

(c) The applicant may request that any test conducted by the Administrator that was a material factor in his decision to reject the application be repeated.

#### **§ 53.11 Cancellation of reference or equivalent method designation.**

(a) *Preliminary finding.* If the Administrator makes a preliminary finding on the basis of any information available to him that a representative sample of a method designated as a reference or equivalent method and offered for sale as such does not fully satisfy the requirements of this part or that there is any violation of the requirements set forth in § 53.9, he may initiate proceedings to cancel the designation in accordance with the following procedures.

(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the FEDERAL REGISTER.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the requirements of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the FEDERAL REGISTER.